UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,138	01/23/2004	Benedicte Charrier	ARNO124164	6095

26389 7590 09/26/2006

CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER	
WORLEY, CATHY KINGDON	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,138	CHARRIER ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2-6,12,15 and 17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-11,13,14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. In response to the communication received on July 3, 2006 from Dennis K. Shelton, the election of group IX, claim 7, along with linking claims 1, 8-11, 13-14, and 16, is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant is advised to amend the claims to read only on the elected invention. This restriction requirement is MADE FINAL.

Specification

2. The abstract of the disclosure is objected to because it is too short and not descriptive enough of the elected invention. The abstract should be between 50 and 150 words in length, and it should mention the organism and gene from which the recited nucleic acids are taken. Correction is required. See MPEP § 608.01(b).

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The specification is objected to because Applicants attempt to incorporate essential material by reference from non-US Patent sources (see page 6 lines 14-24). Essential material can only be incorporated by reference if the reference document is a US Patent. Because the ASK-genes of group II disclosed in the references are recited in the claims, they are considered essential material. Applicant is advised to amend the specification to include the essential material that appears in the references.

Information Disclosure Statement

5. The listing of references in the specification on pages 23-24 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents,

publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

6. Claims 8, 13, and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Regarding claim 8, the nucleic acid recited in claim 1 is "derived from" at least one ASK-gene of group II, and the limitation in claim 8 that the ASK-gene is in the form of a cDNA or genomic DNA does not further limit the process. What other form could the ASK-gene be? Regarding claim 13, what other kind of plant cell could be used in this process besides a monocot or a dicot plant cell? Regarding claim 16, how can a transgenic plant with seeds comprising modified embryos be made without regenerating the transformed cell into a differentiated plant; and what is the difference between being "regenerated to a plant" and regenerating into a "differentiated plant"?

7. Claim 1 is objected to because of the following informalities: there is an unnecessary comma in line 2 between "comprise" and "an". There appears to be a typographical error in line 6; the Applicant is advised to replace "relation" with - - relationship - - . There also appears to be a typographical error in line 7; the Applicant is advised to replace "chromatine" with - - chromatin - - . Appropriate correction is required.

8. Claim 9 is objected to because of the following informalities: the use of the word "being" is awkward. The Applicant is advised to delete the word "being" from line 2 of the claim, and the Applicant is advised to replace "and being" with - - , wherein said regulatory element is - - . Appropriate correction is required.

9. Claim 11 is objected to because of the following informalities: there appears to be a typographical error in line 3. The Applicant is advised to replace "sequences" with - - sequence - - . In addition, the current sentence format is awkward with "in particular a Poly A addition site" appearing immediately after "ASK-gene of group II. The Applicant is advised to rearrange the sentence to insert - - , in particular a Poly A addition site, - - between "termination signal" and "operably linked". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 7-11, 13-14, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in these rejections.

Claims 1 and 7 include a nucleic acid sequence "derived from" at least one ASK-gene of group II. What is meant by "derived from"? What ASK-gene sequences are retained in the claimed nucleic acid sequence? Does the derived sequence only require at least one nucleotide from the ASK-gene?

Claim 1 recites "due to a functional relation between one of the GSK Shaggy kinase and a chromatine remodeling factor, the MEDEA protein". Does this mean there is more than on GSK Shaggy kinase? Or does this mean any relationship between two items selected from the group consisting of a GSK Shaggy kinase, a chromatin remodeling factor, and the MEDEA protein?

Claim 16 recites the limitation "the transformed cells" in line 1. There is insufficient antecedent basis for this limitation in the claim.

11. Claims 1, 7-11, 13-14, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All dependent claims are included in these rejections.

The claims are drawn to a process wherein at least one plant cell is transformed with at least one DNA construct comprising a nucleic acid sequence derived from at least one ASK-gene of group II.

The specification discloses the use of antisense to suppress the expression of two of the endogenous ASK genes (see page 21-22). The essential feature of the nucleic acids used in the claimed process is the ability to suppress the expression of endogenous ASK genes.

The claims are broadly drawn to a process utilizing any nucleic acid sequence "derived from" any ASK-gene of group II to transform a plant of any species. The specification, however, describes only two nucleic acids used for the claimed process, and the process is reduced to practice in Arabidopsis only (see pages 21-22).

A nucleic acid "derived from" an ASK-gene of group II could have as little as one nucleotide from the ASK-gene and still qualify as being "derived from" the gene. Therefore, the genus of molecules encompassed by this recitation is infinitely large. The specification has not provided any guidance about what structures (domains, motifs, or subsequences) are required for the essential function of being able to suppress expression of the endogenous target gene.

Given the breadth of the claims encompassing processes utilizing an infinitely large genus of molecules, only two molecules reduced to practice, and a lack of guidance relating structure to function, the written description requirement has not been met.

12. Claims 1, 7-11, 13-14, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a process wherein at least one plant cell is transformed with at least one DNA construct comprising a nucleic acid sequence derived from at least one ASK-gene of group II. This process is proposed to produce plants with an increased number of storage organs that may contain valuable and commercially interesting substances (see page 2 lines 21-24).

The nature of the invention is a molecular biological approach to suppress expression of endogenous genes which will result in transgenic plants that produce seeds with modified embryo development.

The claims are broadly drawn to the use of any nucleic acid sequence "derived from" an ASK-gene of group II to transform a plant cell of any species. The claims specify that a transgenic plant produced by this method will have seeds with modified embryo development due to a functional relation between one of the GSK Shaggy kinase and a chromatine remodeling factor, the MEDEA protein. Because a nucleic acid "derived from" an ASK-gene need only comprise one nucleotide from the ASK-gene to be considered "derived from" said gene, there is no structural limitations on the nucleic acids encompassed by these claims. Therefore the claims are broadly drawn to any nucleic acid that would result in modified embryo development due to a functional relation between the recited proteins.

The instant specification has only taught the use of antisense to cause suppression of endogenous GSK Shaggy kinase genes in Arabidopsis which results in modified embryos produced by the transformed plants (see pages 21-22). The specification has not taught any nucleic acids other than these two antisense constructs. The specification has not provided any guidance on what other sequences could be utilized in the claimed process. This ground of rejection applies especially to claim 7 in which fragments are recited, and the instant specification has not provided any guidance about what fragments would be effective for

antisense suppression of the targeted endogenous gene. Furthermore, the specification has not taught any species of plant other than Arabidopsis for which the process has been successfully utilized.

The claims encompass the use of antisense in multiple plant species. The specification in the instant application only discloses the use of antisense in Arabidopsis plants (see pages 21-22). Antisense suppression of gene expression is highly unpredictable, and the prior art suggests that success depends on the percent identity between the sequence of the antisense construct and the target gene sequence (see Elomaa et al. (1996) Molecular Breeding, Vol. 2, pp. 41-50; paragraph bridging pages 47-48, in particular). In the prior art, Klee et al. teach that antisense genes would probably be species-specific, and therefore a different antisense gene would be required for each species of plant desired to be transformed (see US Patent # 5,702,933, issued Dec. 30, 1997, column 1 lines 60-65, in particular). Because of the sequence variability between the different genes in different species of plants and because of the inconsistent results taught in the prior art, there is a high degree of unpredictability in the use of antisense to inhibit the expression of different genes.

The process is proposed to produce plants with an increased number of storage organs that may contain valuable and commercially interesting substances (see page 2 lines 21-24). However, the instant specification does not provide

guidance about how one of skill would use Arabidopsis plants for harvesting valuable and commercially interesting substances.

In addition, claim 9 recites the limitation "wherein the DNA construct comprises at least one regulatory element being operably linked to the nucleic acid sequence". Because this limitation further limits claim 1, this means that claim 1 encompasses constructs that do not have a regulatory element operably linked to the nucleic acid sequence. The instant specification has not taught any working examples without a regulatory element, and it would require undue experimentation on the part of one of skill in the art to determine how to use a construct without a regulatory element to practice the claimed process.

Given the breadth of the claims encompassing any method of modifying embryo development due to a functional relation between recited proteins in any plant, and given that there are only two working examples both of which are in Arabidopsis, and a high degree of unpredictability as discussed above, it would require undue experimentation on the part of one of skill in the art to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 8-11, 13-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Finnegan et al. (PNAS (1996) Vol. 93, pp. 8449-8454).

The claims are drawn to a process wherein at least one plant cell is transformed with at least one DNA construct comprising a nucleic acid sequence "derived from" at least one ASK-gene of group II.

Finnegan et al. teach Arabidopsis plants transformed with a MET1 antisense construct that comprises the 35S promoter and nopaline synthase 3' termination signal (see page 8449, right column, second and third paragraphs). The MET1 antisense construct comprises at least a di-nucleotide and this di-nucleotide is "derived from" at least one ASK-gene of group II, therefore, the antisense construct comprises a nucleic acid sequence "derived from" at least one ASK-gene of group II. Further more the transgenic plants comprising the MET1 antisense constructs that have <35% of the wild-type level of methylation exhibit modified embryo development (*superman agamous apetala1* triple mutant phenotype) (see page 8453, right column, second paragraph). This is due to a change in chromatin structure (see page 8453, right column, third paragraph), and chromatin structure is determined, in part, by a functional relationship between GSK3 Shaggy kinase and the MEDEA protein (see page 3 lines 5-10 of the instant specification).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1, 8-11, 13-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al (PMB (1999) Vol. 41, pp. 837-849) in view of Dornelas et al. (PMB (1999) Vol. 39, pp. 137-147).

The claims are drawn to a process wherein at least one plant cell is transformed with at least one DNA construct comprising a nucleic acid sequence derived from at least one ASK-gene of group II.

Zou et al. teach a process for the inhibition of an endogenous kinase wherein an antisense construct is utilized to transform Arabidopsis plants (see page 839, right column, second paragraph).

Zou et al. do not teach the inhibition of an ASK kinase.

Dornelas et al. teach the cDNA sequences of several ASK kinases (see page 139, figure 1).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the process taught by Zou et al. to utilize the cDNAs taught by Dornelas et al. One would have been motivated to

do so because Dornelas et al. teach that the ASK genes are involved in signal transduction pathways that establish cell fate (see page 138, fourth paragraph), and they also teach that their lab is currently making such antisense plants to access additional information concerning the role of the ASK genes on plant development (see page 146 second paragraph).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 7-11, 13-14, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-22 of U.S. Patent No. 6,822,139 B1, issued on Nov. 23, 2004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process of the invention of US Patent No. 6,822,139 utilizes one of the ASK-genes of group II, therefore it is one species of the genus being recited in the instant claims. This species, therefore, anticipates the genus of the instant application.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
Sept. 15, 2006

ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER